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10/538,303

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EXAMINER

HELLING, KAITLYN ELIZABETH

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3739

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/538,303	Applicant(s) DUNLOP, COLIN	
	Examiner KAITLYN E. HELLING	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 15, 16, 18, 19, 21-27, 29, 30 and 32-37 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15, 16, 18, 19, 21-27, 29, 30 and 32-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Entry of Amendment

1. Applicant's amendment filed on November 16, 2009 has been entered. Claims 15, 16, 18, 19, 21-27, 29, 30 and 32-37 remain pending.

Response to Arguments

2. Applicant's arguments with respect to claims 15, 22, 27 and 37 have been considered but are moot in view of the new ground(s) of rejection.
3. Applicant's arguments filed November 16, 2009 with respect to the term "porous" have been fully considered but they are not persuasive. Claim language is given its broadest reasonable interpretation unless given a special definition within applicant's own specification. Therefore, as porous is defined as permitting the movement of fluids or gases through it by way of pores or other passages, the materials of Berke and Tomic-Edgar are porous as they allow air to flow through the material. The term does not preclude the use of an impervious material with hole punches in it.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. Claims 15-16, 18-19, 21,27, 29-30 and 32-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berke (US 5165400) in view of Tomic-Edgar et al (US 6277144 B1) and Irani (US 5405370).

Berke discloses a surgical warming blanket (10) comprising at least two layers (see Fig 5) capable of forming hollow air space between the two layers (hollow legs 13

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and 14, Fig 1) for receiving warmed air from a heating unit (11), the two layers and air space being arranged in operation to form a substantially tubular arrangement at least partially surrounding a patient receiving space (see Fig 1), whereby when warm air is passes into the air space the warm air is delivered to the patient receiving space via the blanket (column 2 lines 34-40), to maintain warm air within the patient receiving space, the patient receiving space being arranged to receive the patient's body and allowing access to the patient's body for surgery without disturbing the blanket (as is clearly shown in Fig 1). Berke does not specifically disclose that one of the two layers of the blanket has a portion of its surface formed of porous material so that the air is delivered to the patient receiving space via the entire surface of the porous material. Berke also does not disclose a blanket base for the patient to lie on.

Tomic-Edgar et al teaches an inflatable patient warming apparatus similar to the Berke apparatus (see Fig 1A), wherein there is an external surface layer (400) constructed of any soft material suited for contact with a patient's body (column 6 lines 52-59). With the configuration taught by Tomic-Edgar, the warmed air is delivered to the patient receiving space via the entire surface of the porous material. Tomic-Edgar also teaches a continuation of one of the layers provides a blanket base within the patient receiving space, arranged for the patient to lie on (column 4 lines 8-19). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified Berke by including an external surface layer as taught by Tomic-Edgar in order to provide a soft material to contact a patient's skin, and by adding the blanket base, as taught by Tomic-Edgar in order to add structural stability to the apparatus.

However, neither Berke nor Tomic-Edgar teaches that the warmed air is delivered to the patient receiving space by diffusing over the entire surface of the porous material at a relatively low velocity so as to have the effect of evenly warming the patient without forming relatively high velocity streams of air. Irani teaches an air blanket (10) arrangement that comprises a barrier layer (14) that is substantially impervious to airflow and a heat transfer layer (18) that are joined together to form a chamber adapted for the reception of warm air (abstract) where the air from the chamber penetrates and uniformly diffuses through the heat transfer layer to gently impinge upon the treated patient (abstract and Col. 3, line 56-Col. 5, line 19). It would have been obvious to one having ordinary skill in the art at the time of the invention to have substituted the porous material of Irani with the materials of Berke and Tomic-Edgar as Irani teaches that using such a material allows for the gentle impinging of the heated air substantially over the entire surface of the blanket (Col. 3, lines 56-63).

Regarding claims 16, 18-19, 21 and 30, Berke in view of Tomic-Edgar and Irani discloses the surgical warming blanket described above, with Berke and the further limitations of wherein the tubular arrangement surrounds the patient receiving space on three sides (see Figs 1 and 2), wherein the surface of the blanket is arranged to be fluid repellent (column 3 line 33-34), and wherein the surgical warming blanket is sized and shaped so that the patient receiving space is arranged to receive a human (see Fig 1) and is also capable of receiving an animal (such as a large dog or a monkey), and a small animal (small being a relative term and including a monkey or small cow) whereby to maintain warmth of the human or animal.

Regarding claims 27, 29 and 32-36, Berke in view of Tomic-Edgar and Irani discloses a method of warming a patient comprising the steps of receiving the patient within a patient receiving space within which the patient's body is accessible for surgery, and passing warmed air into a patient receiving space to keep the patient warm utilizing the surgical warming blanket as described above (see the abstract, column 1 lines 15-24 and column 2 lines 10-11).

6. Claims 22-26 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berke in view of Tomic-Edgar, Irani and Hagopian (US 4963997).

Regarding claims 22-26, Berke in view of Tomic-Edgar and Irani discloses patient warming system as described above, with Berke further teaching a heating unit (11) including a delivery port (opening 16, Fig 3) for delivering warmed air to the patient warming blanket, described above, and a safety monitoring means for automatic shut-off (column 3 lines 6-8); the heating unit being arranged to heat the air to a range of temperatures, including up to 46 degrees C (column 3 lines 3- 6). Berke does not disclose a pressure sensor feedback system. Hagopian teaches an inflatable patient support system (Fig 1) with a control unit (10), pumps (22 and 24) and ports (88 and 90) for delivering air to the device and a feedback means for determining whether a patient warming blanket is attached; wherein the feedback means includes a pressure sensor for sensing back pressure on the air delivery port (column 4 line 65- column 5 line 17). Furthermore, pressure feedback systems are well known in the art. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Berke by adding the pressure sensor feedback system as

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taught by Hagopian to the automatic shut-off safety mechanism in order to appropriately inflate the patient warming blanket to desired values when the blanket is attached.

Regarding claim 37, Berke discloses a surgical warming blanket (10) comprising at least two layers (see Fig 5) capable of forming hollow air space between the two layers (hollow legs 13 and 14, Fig 1) for receiving warmed air from a heating unit (11), the two layers and air space being arranged in operation to form a substantially tubular arrangement at least partially surrounding a patient receiving space (see Fig 1), whereby when warm air is passes into the air space the warm air is delivered to the patient receiving space via the blanket (column 2 lines 34-40), to maintain warm air within the patient receiving space, the patient receiving space being arranged to receive the patient's body and allowing access to the patient's body for surgery without disturbing the blanket (as is clearly shown in Fig 1), a heating unit including a delivery port (opening 16, Fig 3) for delivering warmed air to the patient warming blanket, described above, and a safety monitoring means for automatic shut-off (column 3 lines 6-8), and the heating unit being arranged to heat the air to a range of temperatures, including up to 46 degrees C (column 3 lines 3- 6). Berke does not specifically disclose that a first layer of the two layers of the blanket is formed of porous material so that the air is delivered to the patient receiving space via the entirety of the first layer, a blanket base for the patient to lie on, or a pressure sensor feedback system.

Tomic-Edgar et al teaches an inflatable patient warming apparatus similar to the Berke apparatus (see Fig 1A), wherein there is an external surface layer (400) constructed of any soft material suited for contact with a patient's body (column 6 lines

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52-59). With the configuration taught by Tomic-Edgar, the warmed air is delivered to the patient receiving space via the entire surface of the porous material. Tomic-Edgar also teaches a continuation of one of the layers provides a blanket base within the patient receiving space, arranged for the patient to lie on (column 4 lines 8-19). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified Berke by including an external surface layer as taught by Tomic-Edgar in order to provide a soft material to contact a patient's skin, and by adding the blanket base, as taught by Tomic-Edgar in order to add structural stability to the apparatus.

However, neither Berke nor Tomic-Edgar teaches that the porous material has substantially uniform porosity and wherein warmed air is delivered to the patient receiving space by diffusing over the entirety of the first layer at a relatively low velocity so as to have the effect of evenly warming the patient without forming relatively high velocity streams of air. Irani teaches an air blanket (10) arrangement that comprises a barrier layer (14) that is substantially impervious to airflow and a heat transfer layer (18) that are joined together to form a chamber adapted for the reception of warm air (abstract) where the air from the chamber penetrates and uniformly diffuses through the heat transfer layer (which inherently has a substantially uniform porosity as the entire heat transfer layer is made from the same material) to gently impinge upon the treated patient (abstract and Col. 3, line 56-Col. 5, line 19). It would have been obvious to one having ordinary skill in the art at the time of the invention to have substituted the porous material of Irani with the materials of Berke and Tomic-Edgar as Irani teaches that using

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such a material allows for the gentle impinging of the heated air substantially over the entire surface of the blanket (Col. 3, lines 56-63).

Hagopian teaches an inflatable patient support system (Fig 1) with a control unit (10), pumps (22 and 24) and ports (88 and 90) for delivering air to the device and a feedback means for determining whether a patient warming blanket is attached; wherein the feedback means includes a pressure sensor for sensing back pressure on the air delivery port (column 4 line 65- column 5 line 17). Furthermore, pressure feedback systems are well known in the art. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Berke, Tomic-Edgar and Irani by adding the pressure sensor feedback system as taught by Hagopian to the automatic shut-off safety mechanism in order to appropriately inflate the patient warming blanket to desired values when the blanket is attached.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAITLYN E. HELLING whose telephone number is (571)270-5845. The examiner can normally be reached on Monday - Friday 9:00 a.m. to 5:30 p.m. EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571)272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KAITLYN E. HELLING/
Examiner, Art Unit 3739

/Roy D. Gibson/
Primary Examiner, Art Unit 3739